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One-Year Real-World Outcomes With a Novel Hybrid Full Range of Vision Intraocular Lens

Resultados en vida real a un año con una nueva lente intraocular híbrida de rango completo de visión

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Disclosures

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The authors report no proprietary or commercial interest in any of the materials or methods described in this study.

Abstract

Purpose. To evaluate real-world visual performance, refractive stability, and safety over 12 months following implantation of a novel hybrid extended depth-of-focus (EDOF)–based intraocular lens (IOL) in patients undergoing cataract surgery.

Methods. A prospective, single-center, non-randomized clinical study was conducted at Centro de Ojos Quilmes, Buenos Aires, Argentina. Fifty patients (100 eyes) undergoing bilateral sequential cataract surgery received the Max Vision™ IOL. Visual outcomes included uncorrected and corrected distance visual acuity (UDVA, CDVA) and uncorrected near visual acuity at 32 cm and 40 cm, assessed using logarithmic charts. Refractive outcomes, intraocular pressure (IOP), and safety parameters were recorded preoperatively and at 1 week, 1 month, 6 months, and 12 months postoperatively. The 12-month visit served as the primary endpoint.

Results. Mean patient age was 66.1 ± 7.9 years. UDVA and CDVA improved significantly after surgery and remained stable through 12 months ($p < 0.001$), with a high proportion of eyes achieving 0.1 logMAR or better uncorrected distance vision. Uncorrected near visual acuity at 32 cm and 40 cm showed significant and sustained improvement compared with preoperative values ($p < 0.001$). Spherical equivalent refraction demonstrated high predictability relative to the emmetropic target and remained stable throughout follow-up. No eyes experienced a loss of ≥2 lines of CDVA. One posterior capsular rupture occurred and was managed without sequelae. No clinically significant postoperative complications,

posterior capsular opacification, IOL decentration, tilt, or retinal abnormalities were observed during follow-up.

Conclusions. In this real-world 12-month evaluation, the Max Vision™ IOL demonstrated excellent and stable distance visual acuity, sustained functional near vision, high refractive predictability, and a favorable safety profile. These findings support further investigation of this hybrid optical concept in larger and comparative studies.

Keywords: Cataract surgery; Extended depth-of-focus intraocular lens; Visual outcomes; Refractive accuracy; Real-world evidence; Multifocal soft

Resumen

Objetivo. Evaluar el desempeño visual en condiciones de vida real, la estabilidad refractiva y la seguridad durante 12 meses tras la implantación de una nueva lente intraocular (LIO) híbrida basada en profundidad de foco extendida (EDOF) en pacientes sometidos a cirugía de catarata.

Materiales y métodos. Se realizó un estudio clínico prospectivo, unicéntrico y no aleatorizado en el Centro de Ojos Quilmes, Buenos Aires, Argentina. Cincuenta pacientes (100 ojos) sometidos a cirugía bilateral secuencial de catarata recibieron la LIO Max Vision™. Los resultados visuales incluyeron la agudeza visual lejana no corregida y corregida (UDVA y CDVA) y la agudeza visual cercana no corregida a 32 cm y 40 cm, evaluadas con cartillas logarítmicas. Los resultados refractivos, la presión intraocular (PIO) y los parámetros de seguridad se registraron en el preoperatorio y a la semana, al mes, a los 6 meses y a los 12 meses del postoperatorio. La visita de los 12 meses se consideró el

punto principal de evaluación.

Resultados. La edad media de los pacientes fue de 66,1 ± 7,9 años. La UDVA y la CDVA mejoraron significativamente después de la cirugía y se mantuvieron estables hasta los 12 meses ($p < 0,001$), con una alta proporción de ojos que alcanzaron una visión lejana no corregida de 0,1 logMAR o mejor. La agudeza visual cercana no corregida a 32 cm y 40 cm mostró una mejoría significativa y sostenida en comparación con los valores preoperatorios ($p < 0,001$). La refracción equivalente esférica mostró alta predictibilidad respecto del objetivo emetrópico y permaneció estable durante todo el seguimiento. Ningún ojo presentó una pérdida de ≥2 líneas de CDVA. Se produjo una ruptura de cápsula posterior, que fue resuelta sin secuelas. Durante el seguimiento no se observaron complicaciones postoperatorias clínicamente significativas, opacificación capsular posterior, descentramiento o inclinación de la LIO, ni alteraciones retinianas.

Conclusiones. En esta evaluación en vida real a 12 meses, la LIO Max Vision™ mostró una agudeza visual lejana excelente y estable, visión cercana funcional sostenida, alta predictibilidad refractiva y un perfil de seguridad favorable. Estos hallazgos respaldan la realización de estudios más amplios y comparativos para profundizar la evaluación de este concepto óptico híbrido.

Palabras clave: cirugía de catarata; lente intraocular de profundidad de foco extendida; resultados visuales; precisión refractiva; evidencia en vida real; multifocal suave.

Introduction

Advances in intraocular lens (IOL) technology have progressively shifted the goals of cataract surgery from visual rehabilitation alone toward greater spectacle independence and improved functional vision across multiple distances.[1-4] In this context, extended depth-of-focus (EDOF) and low-add multifocal IOL designs have emerged as alternatives intended to balance high-quality distance visual acuity with usable intermediate and near vision, while reducing photic phenomena commonly associated with traditional multifocal optics.[1,5,6] Nevertheless, clinical outcomes with presbyopia-correcting IOLs may vary substantially depending on optical design, patient selection, and real-world surgical conditions.[7,8]

The Max Vision™ intraocular lens (OphthalmoPro GmbH, St. Ingbert, Germany) represents a hybrid optical concept that combines elements of EDOF technology with a low-add, soft diffractive multifocal design.[9] Rather than relying on a single optical principle, the lens integrates distinct functional zones on its anterior and posterior surfaces to broaden the range of vision while aiming to preserve distance visual quality and mitigate photic phenomena. According to the manufacturer's design rationale, this combined approach seeks to optimize light utilization and provide a smooth transition between distance, intermediate, and near vision under physiological pupil conditions.[9]

At present, publicly available clinical data on this lens are scarce, and peer-reviewed evidence regarding its visual outcomes and safety profile remains limited. Recently, early 1-month real-world outcomes with this lens were reported in a prospective cohort of 50 patients (100 eyes), showing substantial improvements in distance and near visual acuity, early refractive accuracy, and no major short-term safety concerns.[10] The present study extends that initial clinical experience by reporting 12-month longitudinal outcomes in the same real-world setting, with emphasis on visual stability, refractive predictability, and safety

over time. Based on the contemporary classification of presbyopia-correcting intraocular lenses proposed by Fernández et al.,[11] the optical concept of the Max Vision™ IOL may be categorized as a full range of vision intraocular lens with a soft transition profile, combining EDOF features with a low-add diffractive multifocal component. This category is intended to provide functional vision across distances while minimizing abrupt energy redistribution and associated photic phenomena.

Early clinical experience with novel IOL platforms is particularly relevant when evaluated under routine clinical practice conditions, as outcomes observed in controlled or highly selective trials may not fully reflect real-world performance. In addition, regional data are important, as surgical practices, patient expectations, and visual demands may differ across populations. Although an initial 1-month clinical report is now available, longitudinal real-world evidence on the Max Vision™ IOL from Latin America remains very limited. Using a prospective protocol designed to reflect routine clinical practice, the present study aimed to evaluate the visual performance, refractive stability, and safety profile associated with implantation of the Max Vision™ intraocular lens over 12 months.

Methods

Study design and ethical considerations

A prospective, single-center, non-randomized clinical study was conducted to evaluate the visual performance of a novel IOL implanted in patients undergoing cataract surgery at Centro de Ojos Quilmes, Buenos Aires, Argentina. The study protocol was reviewed and approved by the institutional ethics committee. All participants provided written informed

consent before enrollment, and the study was conducted in accordance with the principles of the Declaration of Helsinki. The 1-month outcomes from this prospective cohort were previously reported as an initial clinical evaluation of the same IOL.[10] The present manuscript represents the planned longitudinal extension of that cohort and focuses on visual, refractive, and safety outcomes through 12 months of follow-up.

Study population

Patients older than 50 years with bilateral age-related cataract and a desire to achieve spectacle independence for most daily activities were considered eligible. From September 2024 to December 2024, consecutive patients scheduled for bilateral, non-simultaneous cataract surgery (sequential procedures separated by one week) were recruited and offered implantation of the Max Vision™ IOL.

Patients were excluded if they were unable to provide informed consent or were younger than 50 years. Ocular exclusion criteria included microphthalmia, congenital ocular abnormalities, pigment dispersion syndrome, corneal decompensation, unstable keratoconus or irregular astigmatism, pathological pupil reactions, or any ocular condition expected to limit postoperative visual acuity to worse than 0.5 decimal, such as amblyopia, nystagmus, retinitis pigmentosa, aniridia, advanced macular disease, or other progressive retinal degenerations, including age-related macular degeneration. Additional exclusions comprised active or chronic ocular diseases, including severe uveitis, proliferative diabetic retinopathy, uncontrolled glaucoma, iris atrophy, severe zonular weakness, pseudoexfoliation syndrome, pseudophacodonesis, narrow-angle glaucoma, macular pathology, or a history of complicated cataract surgery. Patients with any prior ocular surgery

(e.g., radial keratotomy, PRK, LASIK) or planned ocular surgery during the study period were also excluded.

Systemic exclusion criteria included autoimmune, infectious, immunosuppressive, or inflammatory diseases (such as Sjögren's syndrome, rheumatoid arthritis, HIV infection, hepatitis, or tuberculosis), as well as the chronic use of systemic medications known to interfere with visual function (e.g., long-term corticosteroids). Subjects with high myopia greater than 10.00 diopters were excluded. Finally, employees, relatives, or close associates of ophthalmic industry companies or investigational clinics were not eligible to participate.

Baseline characteristics and outcome measures

Demographic and ocular biometric data were recorded, including age, sex, axial length, anterior chamber depth, spherical equivalent, corneal curvature radii (K1 and K2), and the implanted IOL power.

Primary visual performance outcomes included uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), assessed using a Snellen chart and subsequently converted to the logarithm of the minimum angle of resolution (logMAR) scale for analysis. Near visual acuity testing was performed at fixed distances (32 cm and 40 cm), with careful examiner control of testing distance. The primary endpoint of the study was visual and refractive performance at 12 months postoperatively.

Safety outcomes included the proportion of eyes experiencing a loss of two or more lines of corrected distance visual acuity, intraocular pressure (IOP), and the presence of posterior capsular opacification (PCO). IOP was assessed preoperatively and at 1 day, 1 week, 1 month, 6 months, and 12 months postoperatively, using the iCare IC-200 tonometer (iCare,

iCare Finland Oy, Vantaa, Finland). All other outcomes were assessed preoperatively and at 1 week, 1 month, 6 months, and 12 months postoperatively.

Intraoperative and postoperative safety assessment

Intraoperative and postoperative complications were systematically assessed in all cases. Intraoperative events were recorded at the time of surgery. Postoperative safety evaluation was performed at each follow-up visit through slit-lamp biomicroscopy, with specific attention to the anterior segment. Postoperative examinations included assessment for anterior chamber abnormalities, corneal edema, wound integrity (Seidel test), anterior chamber inflammatory reaction, and posterior capsular opacification (PCO). Anterior chamber inflammation was graded clinically, and any reaction exceeding a mild physiological response was recorded as an adverse event. The presence of any other ocular finding potentially related to the surgical procedure or the implanted IOL was also documented. In addition to routine slit-lamp evaluation, IOL centration and stability were clinically assessed at each postoperative visit. Lens centration was evaluated by slit-lamp biomicroscopy under mydriasis, using the visual axis and pupil center as reference points. Any clinically evident IOL decentration or tilt was recorded when present, based on the examiner's judgment during anterior segment examination. No quantitative imaging-based measurements were performed as part of this initial real-world evaluation. PCO was clinically assessed by slit-lamp biomicroscopy at each postoperative visit.

In addition to anterior segment evaluation, posterior segment safety was assessed as part of the study protocol. A dilated fundus examination was performed preoperatively and at the 12-month postoperative visit using binocular indirect ophthalmoscopy, conducted by the institutional retina service, in order to evaluate retinal status and to rule out posterior segment pathology. Furthermore, slit-lamp biomicroscopy was routinely performed at 1

month, 6 months, and 12 months postoperatively with particular attention to signs suggestive of macular involvement, including the presence of cystoid macular edema. Any clinical finding raising suspicion of posterior segment complications was documented and managed according to standard clinical practice.

Surgical and perioperative procedures

Ocular biometry was performed using the ARGOS optical biometer (Alcon, Fort Worth, TX, USA). IOL power calculations were conducted using the Barrett formula, targeting emmetropia in both eyes for distance vision. All surgical procedures were performed by a single experienced surgeon (G.V., >20 years of experience) using standard phacoemulsification with direct horizontal chop, employing the Constellation Vision System (Alcon, Fort Worth, TX, USA). Preoperative assessments, postoperative follow-up examinations, and data collection were performed by an independent investigator (T.M.C.) and medical collaborators. The operating surgeon was not involved in postoperative data acquisition to minimize potential observer bias.

Intraocular lens design and characteristics

The Max Vision™ IOL is a foldable, single-piece, hydrophobic acrylic intraocular lens with a clear optic and a heparin-modified surface.[9] The optical design combines a diffractive posterior surface with focal components for distance and near vision, and a refractive, aspheric anterior surface incorporating EDOF technology. The central optic comprises a soft diffractive zone of approximately 4.0 mm in diameter, with a gradual transition toward a refractive peripheral zone. This smooth transition between diffractive and refractive regions is intended to promote balanced light distribution and reduce interference phenomena,

particularly under mesopic and scotopic pupil conditions. As pupil diameter increases, light distribution progressively favors distance vision, which may contribute to reduced perception of halos and glare. The anterior surface incorporates a higher-order aspheric EDOF profile designed to increase depth of focus through controlled induction of optical aberrations, enabling a continuous range of functional vision rather than discrete focal points. In addition, the combination of refractive and diffractive elements is intended to compensate for chromatic aberration, potentially enhancing contrast and image sharpness. The lens has a 6.0 mm optic diameter, an overall diameter of 13.0 mm, and is available in powers ranging from +6.0 to +30.0 diopters, with a nominal near addition of +2.8 D at the IOL plane.[9]

Statistical analysis

Descriptive statistics were calculated for all study variables. Data distribution was assessed for normality before inferential testing. Because both eyes from each patient were included, descriptive summaries are reported at the eye level. To account for within-subject inter-eye correlation, longitudinal inferential analyses were additionally confirmed in a patient-level sensitivity analysis by averaging both eyes for each participant at each time point and applying repeated-measures analysis of variance across follow-up visits. The patient-level sensitivity analysis yielded conclusions consistent with the eye-level trends. A two-sided p value < 0.05 was considered statistically significant. All enrolled patients completed the planned 12-month follow-up; therefore, no imputation for missing data was required. This study was designed as a real-world clinical evaluation of a newly introduced intraocular lens. Accordingly, a target sample size of 50 patients (100 eyes) was predefined a priori based on recruitment feasibility within the planned study period and on the need to obtain reliable descriptive and longitudinal estimates of visual performance and safety. Given the exploratory nature of this early clinical experience and the absence of published longitudinal

clinical data for this IOL at the time of study design, no formal hypothesis-driven power calculation was performed. Statistical analyses were performed using XLMiner Analysis ToolPak (Frontline Systems, Inc., Incline Village, NV, USA).

Results

Demographic and preoperative characteristics

A total of 50 patients (100 eyes) were included in the analysis. All enrolled patients completed the planned 12-month follow-up. The study population comprised 24 women and 26 men, with a mean age of 66.1 ± 7.9 years (range, 50–80 years). Baseline demographic data and preoperative ocular biometric characteristics of the operated eyes are summarized in Table 1.

Table 1. Preoperative ocular characteristics of the study population

Parameter	Value
Axial length (mm)	23.4 ± 0.5 (21.8–24.7)
Anterior chamber depth (mm)	3.2 ± 0.3 (2.3–4.1)
K1 (D)	43.2 ± 1.4 (40.1–47.2)
K2 (D)	43.8 ± 1.5 (40.6–47.8)

K1 axis (°)	91.4 ± 62.3 (1–179)
K2 axis (°)	90.3 ± 40.3 (4–175)
IOL power (D)	22.0 ± 1.2 (19.5–24.5)
Target refraction (D)	−0.02 ± 0.30 (−0.50 to 1.50)

Surgical outcomes and safety

The mean incision size was 2.5 ± 0.1 mm (range, 2.4–2.8 mm), and the mean incision site was 127.3 ± 18.9° (range, 70–135°). A posterior capsular rupture occurred in 1 of 100 eyes (1.0%). In this case, the procedure was completed without further complications, with successful placement of the IOL in the ciliary sulcus. No additional intraoperative complications were recorded. No clinically significant postoperative complications were observed at any follow-up visit. Slit-lamp examinations did not reveal relevant anterior chamber abnormalities, persistent corneal edema, wound leakage, or inflammatory reactions exceeding physiological postoperative findings. No clinically relevant IOL decentration or tilt was observed, and all implanted lenses remained well centered and stable throughout follow-up. No cases of PCO were detected during the 12-month follow-up. Dilated fundus examination performed preoperatively and at 12 months did not reveal any new retinal pathology or clinically relevant changes attributable to surgery or IOL implantation. Mean intraocular pressure showed a transient increase on postoperative day 1, followed by a progressive reduction and stabilization below baseline values from month 1 onward; no eye required additional hypotensive therapy.

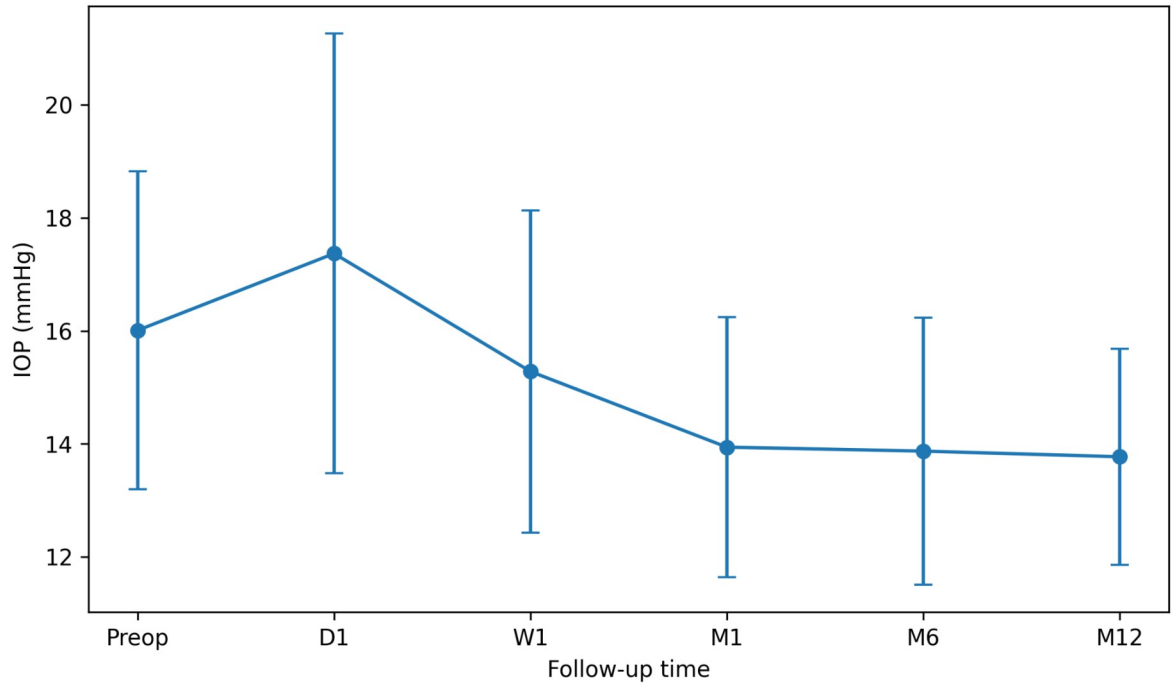

Figure 1. Mean intraocular pressure (IOP) over time from preoperative assessment to 12 months postoperatively. Data are presented as mean ± standard deviation. A transient increase was observed on postoperative day 1, followed by a progressive reduction and stabilization below baseline values from month 1 onward.

Visual and refractive outcomes

Because both eyes of each participant were included, a patient-level sensitivity analysis averaging both eyes at each visit was also performed to account for inter-eye correlation. This analysis yielded the same overall conclusions, with significant longitudinal effects maintained for visual, refractive, and intraocular pressure outcomes. Visual acuity and refractive outcomes over time are summarized in Table 2, whereas intraocular pressure is shown in Figure 1. A significant improvement in UDVA and CDVA was observed from the preoperative visit to all postoperative time points ($p < 0.001$).

The distribution of CDVA line changes relative to baseline is shown in Figure 2; no eyes experienced a loss of two or more lines of CDVA at any postoperative visit. The cumulative distribution of UDVA and CDVA at 12 months is illustrated in Figure 3, demonstrating a high proportion of eyes achieving 0.1 logMAR or better uncorrected distance vision, with excellent corrected distance visual acuity.

Mean spherical equivalent showed a marked reduction from the preoperative value and remained stable throughout follow-up ($p < 0.001$). Refractive stability was maintained from month 1 through month 12. The distribution of postoperative spherical equivalent relative to the emmetropic target (0.00 D) at 12 months is shown in Figure 4, indicating high refractive accuracy. Longitudinal changes in distance visual acuity expressed in logMAR over the 12-month follow-up period are illustrated in Figure 5, showing early improvement and sustained stability over time. Near visual acuity at 32 cm and 40 cm also improved significantly after surgery and remained stable through month 12 ($p < 0.001$ for all comparisons). Finally, at 12 months, 91% of eyes were within ±0.50 D of the emmetropic target and all eyes were within ±1.00 D.

Table 2. Visual acuity and refractive outcomes over time

Parameter	Preop	W1	M1	M6	M12	*p*
SE (D)	1.16 ± 1.7 (−3.75 to 5.50)	0.07 ± 0.4 (−1.0 to 1.25)	0.06 ± 0.4 (−1.25 to 1.25)	0.07 ± 0.3 (−0.75 to 1.0)	0.05 ± 0.3 (−0.75 to 1.0)	<0.001
UDVA (logMAR)	0.58 ± 0.24 (0.10 to 1.00)	0.03 ± 0.08 (0.00 to	0.01 ± 0.03 (0.00 to 0.20)	0.01 ± 0.03 (-0.05 to	0.01 ± 0.03 (-0.05–0.1)	<0.001

		0.40)		0.18)		
CDVA (logMAR)	0.18 ± 0.20 (0.00 to 0.80)	0.02 ± 0.07 (0.00 to 0.40)	-0.001 ± 0.01 (-0.1 to 0.0)	−0.007 ± 0.02 (−0.10 to 0.01)	0.009 ± 0.02 (−0.05 to 0.01)	<0.001
UNVA 32 cm (logMAR)	0.64 ± 0.18 (0.20 to 1.00)	0.26 ± 0.12 (−0.10 to 0.60)	0.20 ± 0.10 (−0.10 to 0.50)	0.2 ± 0.10 (−0.10 to 0.50)	0.2 ± 0.09 (−0.10 to 0.50)	<0.001
UNVA 40 cm (logMAR)	0.61 ± 0.15 (0.20 to 1.00)	0.20 ± 0.14 (−0.20 to 0.70)	0.13 ± 0.11 (−0.20 to 0.50)	0.13 ± 0.11 (−0.20 to 0.50)	0.14 ± 0.11 (−0.20 to 0.50)	<0.001

W: week; M: months; SE: spherical equivalent; UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity; UNVA: uncorrected near visual acuity.

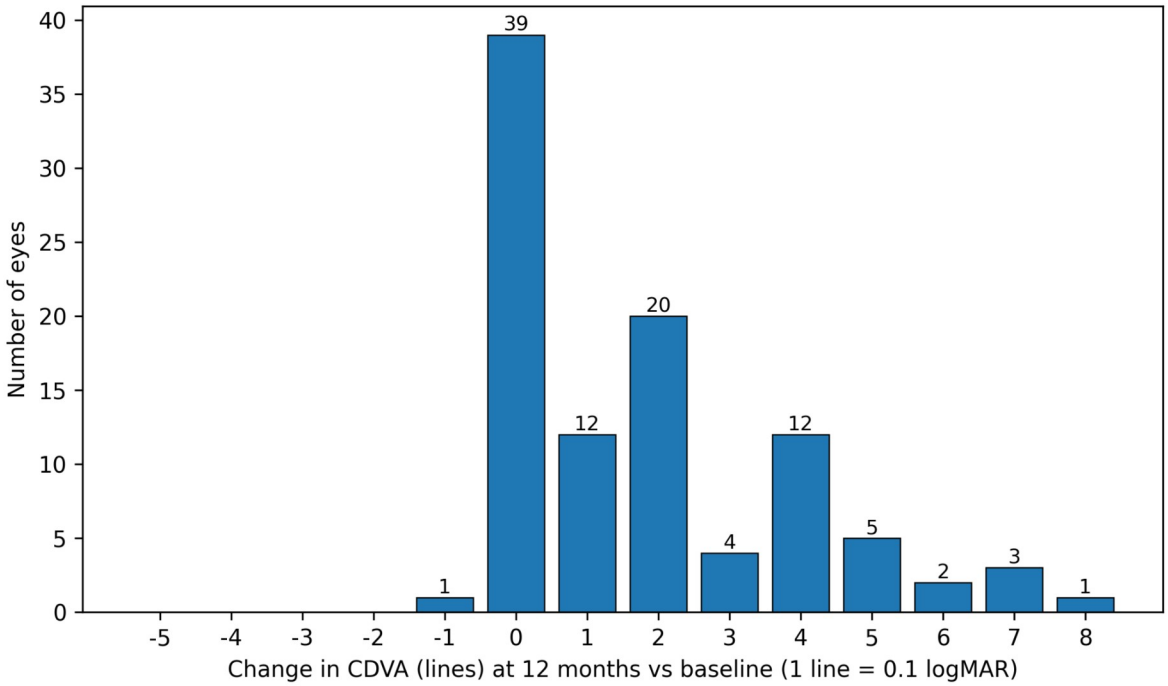

Figure 2. Change in corrected distance visual acuity (CDVA) lines at 12 months relative to baseline (1 line = 0.1 logMAR). Positive values indicate line gain.

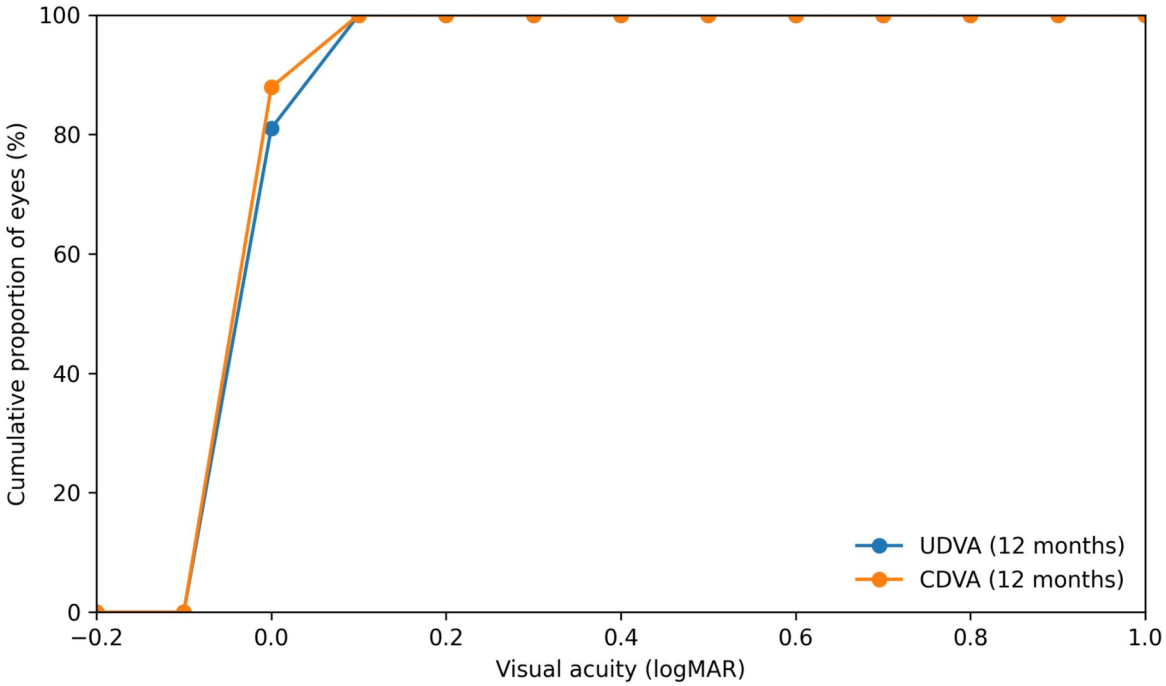

Figure 3. Cumulative distribution of uncorrected (UDVA) and corrected (CDVA) distance visual acuity at 12 months postoperatively

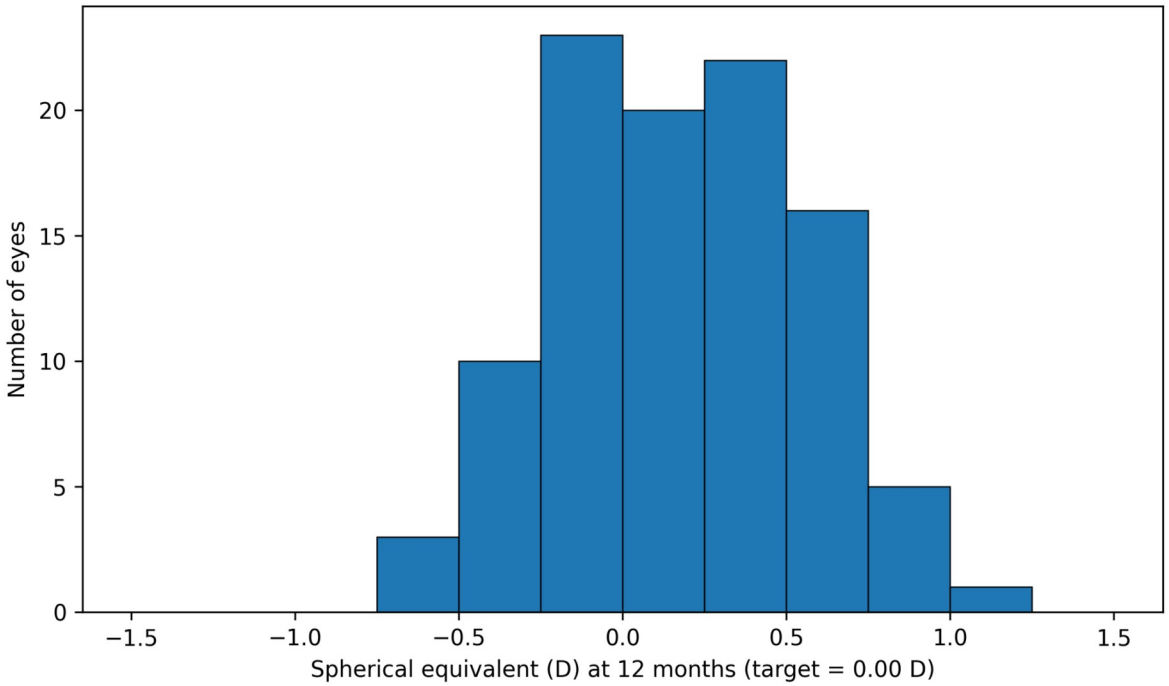

Figure 4. Distribution of postoperative spherical equivalent at 12 months relative to the emmetropic target (0.00 D).

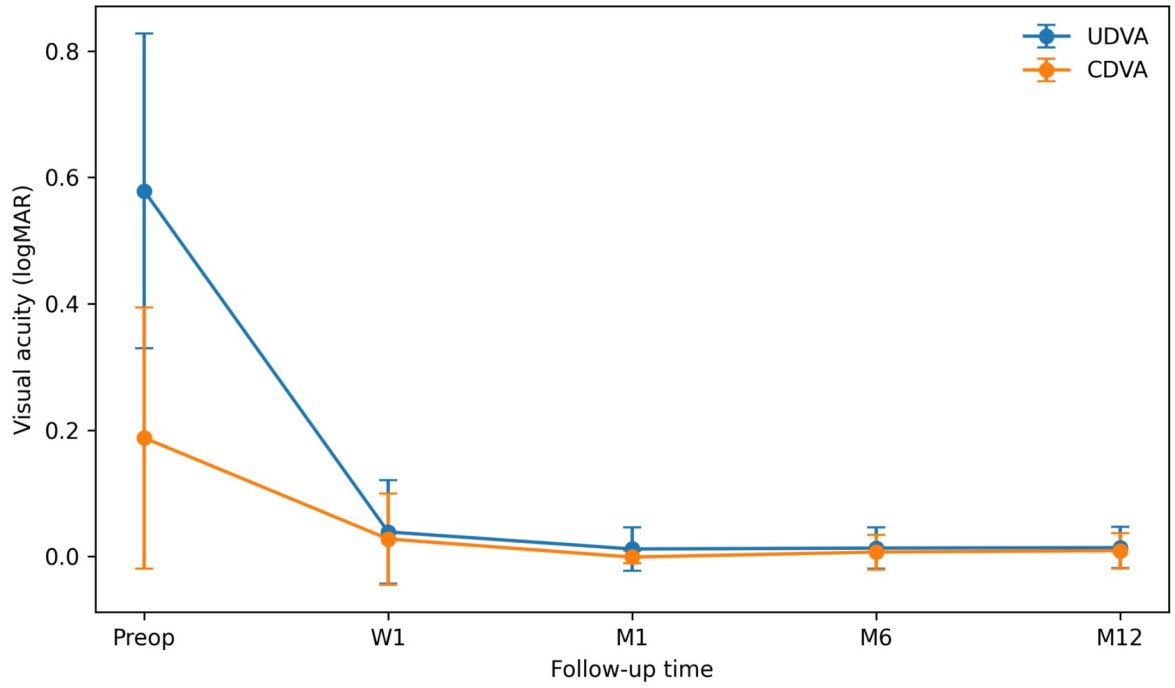

Figure 5. Longitudinal changes in UDVA and CDVA (mean ± SD) from baseline to 12 months.

Discussion

Building on our recently published 1-month report,[10] the present study provides the 12-month longitudinal real-world evaluation of the Max Vision™ intraocular lens. In a cohort of 50 patients (100 eyes) undergoing bilateral sequential cataract surgery, the lens demonstrated excellent and stable distance visual outcomes, sustained functional near vision at 32 and 40 cm, high refractive predictability relative to an emmetropic target, and a favorable safety profile over one year. To our knowledge, this represents the first longitudinal clinical report of this intraocular lens in Latin America, with very limited longer-term clinical data currently available elsewhere.

Distance visual performance was a key finding of this study. Both uncorrected and corrected distance visual acuity improved significantly after surgery and remained stable throughout the 12-month follow-up. Cumulative distribution analysis demonstrated a high proportion of eyes achieving 0.1 logMAR or better uncorrected distance vision, with excellent corrected distance acuity. Importantly, no eyes experienced a loss of two or more lines of CDVA at any postoperative time point, supporting the optical and surgical safety of the lens in routine clinical practice. These findings are consistent with previously reported outcomes for EDOF and low-add multifocal IOLs, which aim to preserve high-quality distance vision while extending the functional range compared with traditional multifocal designs.[1,5,6] The sustained distance performance observed over 12 months aligns with the intended design concept of the Max Vision™ IOL as a full range of vision lens with a soft transition profile.

Refractive outcomes further support the clinical performance of the lens. Spherical equivalent refraction showed a marked reduction from preoperative values and remained stable from the early postoperative period through month 12. The distribution of postoperative spherical equivalent relative to the emmetropic target demonstrated high refractive accuracy, with the majority of eyes within ±0.50 D and nearly all within ±1.00 D. This level of predictability meets contemporary standards for reporting outcomes of IOL-based refractive surgery and is particularly relevant for lenses designed to provide extended functional vision, in which residual refractive error may negatively impact visual performance and patient satisfaction.[6]

Near visual acuity at both 32 cm and 40 cm improved significantly after surgery and remained stable throughout follow-up, without compromising distance vision. Although defocus curve analysis and formal intermediate vision testing are commonly included in

controlled clinical trials, such assessments are not routinely performed in standard postoperative cataract surgery practice. As emphasized in recent reviews, guidelines, and clinical studies,[1,2,4,6,12-14] evaluating near vision at commonly used reading distances under real-world conditions provides clinically meaningful information on functional performance. The sustained near visual acuity observed at one year suggests that the functional range of vision achieved with this lens is durable over time.

The visual outcomes observed in this study may be partly explained by the optical design of the Max Vision™ IOL, which combines extended depth-of-focus characteristics with a low-add, soft diffractive multifocal profile. Rather than creating sharply separated focal points, this hybrid concept is intended to broaden defocus tolerance while maintaining a continuous retinal image. Such an approach may help preserve distance visual quality, reduce abrupt transitions between focal planes, and optimize light utilization. In this context, the excellent distance acuity, high refractive predictability, and stable functional near vision observed over 12 months are consistent with an optical strategy that prioritizes depth-of-focus extension over strong diffractive energy redistribution.[15,16] Although the present study did not include objective optical quality metrics, the absence of clinically relevant losses in CDVA and the stability of visual outcomes over time support the clinical viability of this design concept.

The safety profile observed in this study was favorable. Only one posterior capsular rupture occurred, which was managed intraoperatively without further complications. No clinically significant postoperative adverse events were detected during the 12-month follow-up. Intraocular pressure showed a transient early postoperative increase followed by normalization and sustained reduction relative to baseline. No cases of posterior capsular opacification requiring treatment were observed, and dilated fundus examinations at 12

months did not reveal new retinal pathology. These findings are consistent with the safety profiles reported for modern EDOF and presbyopia-correcting IOLs implanted using standard phacoemulsification techniques.[1,4,6]

Several limitations should be acknowledged. First, this was a single-center, non-randomized study, which may limit generalizability. Second, although follow-up extended to 12 months, longer-term outcomes remain to be evaluated. Third, quality-of-vision endpoints were not formally assessed. In particular, photic phenomena (eg, glare, halos, starbursts), contrast sensitivity, and objective optical quality metrics were not quantified. Also, both eyes from each patient were included in the analysis. Although a patient-level sensitivity analysis yielded consistent results, some degree of within-subject inter-eye correlation should still be considered when interpreting the findings. Given the intended optical concept of the Max Vision™ IOL and the favorable functional performance observed, future studies should incorporate standardized dysphotopsia questionnaires, contrast sensitivity testing, and wavefront- or aberrometry-based analyses to better characterize visual quality and potential trade-offs.[17-20] In addition, although no clinically relevant IOL decentration or tilt was observed on slit-lamp examination, quantitative imaging-based assessment was not performed. Future investigations incorporating anterior segment imaging could help define the tolerance of this optical design to decentration and tilt. Comparative studies against established enhanced monofocal, EDOF, and low-add multifocal platforms, as well as evaluations incorporating mini-monovision strategies, represent important areas for future research.

Conclusion

In conclusion, this real-world 12-month evaluation suggests that implantation of the Max Vision™ intraocular lens is associated with excellent and stable distance visual acuity, sustained functional near vision, high refractive predictability, and a favorable safety profile over the first postoperative year. These findings extend the early clinical evidence for this hybrid optical concept and support further investigation in larger cohorts and comparative studies to better define its long-term role in contemporary cataract and refractive lens surgery.

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